

**COMMONWEALTH OF VIRGINIA
STATE AIR POLLUTION CONTROL BOARD**

**REGULATORY ANALYSIS DOCUMENT FOR
PROPOSED REGULATION REVISION S97
CONCERNING**

**HOSPITAL/MEDICAL/INFECTIOUS WASTE INCINERATORS
(9 VAC 5 CHAPTER 40)**

PROVISIONS AFFECTED

Hospital/medical/infectious waste incinerators (Rule 4-44), Article 44 (9 VAC 5-40-6000 et seq.) of 9 VAC 5 Chapter 40.

STATEMENT OF PURPOSE

The purpose of the regulation is to establish emission standards that will require the owners of hospital/medical/infectious waste incinerators (HMIWIs) to limit emissions of organics (such as dioxins/furans), metals (such as particulate matter), and acid gases (such as sulfur dioxide and hydrogen chloride) to a specified level necessary to protect public health and welfare. The regulation is being proposed to meet the requirements of § 111(d) and § 129 of the federal Clean Air Act, and 40 CFR Part 60 Subpart Ec of federal regulations.

STATEMENT OF STATUTORY AUTHORITY

Section 10.1-1308 of the Virginia Air Pollution Control Law (Title 10.1, Chapter 13 of the Code of Virginia) authorizes the State Air Pollution Control Board to promulgate regulations abating, controlling and prohibiting air pollution in order to protect public health and welfare. Written assurance from the Office of the Attorney General that the State Air Pollution Control Board possesses the statutory authority to promulgate the proposed regulation and that the proposed regulation comports with the applicable state and/or federal law is attached.

STATEMENT OF LEGAL REQUIREMENTS

The identification of (i) the source(s) of the federal legal requirements to promulgate the contemplated regulation, (ii) the scope of the requirements provided, and (iii) the extent to which the authorized rulemaking is mandatory or discretionary may be found below. A copy of all cited legal provisions is attached or may be found at the internet sites listed below.

Federal Clean Air Act (CAA):

<http://www.epa.gov/ttn/oarpg/gener.html>

Code of Federal Regulations (CFR):

<http://www.access.gpo.gov/nara/cfr/cfr-retrieve.html>

Federal Register (FR):

http://www.gpo.gov/su_docs/aces/aces140.html

HMIWI emissions are a "designated" pollutant under § 111(d) of the Clean Air Act. Designated pollutants are pollutants which are not included on a list published under § 108(a) ("criteria" pollutants), or § 112(b)(1)(A) ("hazardous" pollutants), but for which standards of performance for new sources have been established under § 111(b). When the U.S. Environmental Protection Agency (EPA) establishes a new source performance standard (NSPS), states are required to develop standards for existing facilities based on EPA emission guidelines. Designated pollutant controls are critical for two reasons. First, only a limited number of air pollutants potentially harmful to human health are regulated at the federal level. Second, health risks from small exposures to designated air pollutants can be high, depending on the substances involved.

EPA has determined that HMIWIs should be regulated under § 111 (NSPSs) because:

1. HMIWI emissions may be reasonably anticipated to contribute to the endangerment of public health and welfare.
2. The range of health and welfare effects and the range and uncertainties of estimated cancer risks do not warrant listing HMIWI emissions as a hazardous pollutant under § 112.
3. Section 112 could not be used to address particular constituents or subgroups of emissions (such as hydrogen chloride).
4. Section 111(d) would permit a more thorough evaluation of existing HMIWIs at the state level than would be feasible in a general rulemaking at the federal level.

The 1990 Clean Air Act Amendments added a new § 129 that applies to solid waste incinerators, including HMIWIs. Section 129 and its associated standards were promulgated because EPA determined that incinerator emissions cause or contribute significantly to air pollution which may reasonably be expected to endanger public health and welfare. The intended effect of the standards and guidelines is to form a basis for state action to develop state regulations controlling HMIWI emissions to the level achievable by the best demonstrated system of continuous emission reduction, considering costs, non-air quality health and environmental impacts, and energy requirements.

Section 129 directs that the standards and guidelines for HMIWIs be broadened, and provides the schedule for this activity. Regulating HMIWI emissions for new sources under § 111(b) establishes HMIWI emissions as a designated pollutant, and requires EPA to promulgate guidelines under § 111(d) for states to use in developing regulations to control pollutants from existing HMIWIs. Emissions guidelines for existing HMIWIs have been promulgated under §§ 111(d) and 129. In order for §§ 111 and 129 to be effected, the specific guidelines are promulgated in the Code of Federal Regulations (CFR) (subpart Ce of 40 CFR 63). State regulations must be at least as stringent as the guidelines.

The final rule published by EPA in the Federal Register of September 15, 1997 (62 FR 48348) applies to existing HMIWIs built on or before June 20, 1996.

COMPARISON WITH LEGAL REQUIREMENTS

The proposed regulation is not more restrictive than the applicable legal requirements.

DESCRIPTION OF CHANGES

The proposed provisions are detailed below according to citations to the appropriate sections of the regulation.

1. The regulation identifies the sources and geographic areas to which the regulation applies, as well as exemptions [9 VAC 5-40-6000].
2. Terms unique to the article are defined [9 VAC 5-40-6010].
3. Emission limits for particulate matter, carbon monoxide, dioxins/furans, hydrogen chloride, sulfur dioxide, nitrogen oxides, lead, cadmium, and mercury are established [9 VAC 5-40-6020 through 9 VAC 5-40-6100].
4. Cross references to existing state requirements for visible emissions, fugitive dust/emissions, odor, and toxic pollutants are provided [9 VAC 5-40-6110 through 9 VAC 5-40-6140].
5. HMIWI operator training and qualification requirements are specified [9 VAC 5-40-6150].
6. Waste management plans are required. The regulation includes required elements of such plans, which are intended for sources to separate certain components of solid waste from the health care waste stream in order to reduce the amount of toxic emissions from the incinerated waste [9 VAC 5-40-6160].
7. The regulation requires that sources achieve and maintain compliance with the emission limitations and work practices, along with requirements for inspections; compliance, emissions testing, and monitoring; recordkeeping and reporting; and compliance schedules [9 VAC 5-40-6170 through 9 VAC 5-40-6200].
8. Cross references to existing state requirements for registration, facility and control equipment maintenance or malfunction; and permits are provided [9 VAC 5-40-6210 through 9 VAC 5-40-6230].

STATEMENT OF CONCLUSIONS AND NEED

The proposed regulation is essential (i) to protect the health, safety or welfare of citizens, and (ii) for the efficient and economical performance of an important governmental function. The reasoning for this conclusion, along with a discussion of the problems the regulation's provisions are intended to solve, is set forth below.

HMIWI emissions are known or suspected of causing cancer, nervous system damage, developmental abnormalities, reproductive impairment, immune suppression, liver disfunction, hormone imbalance, and other serious health effects. Control of such emissions will reduce and prevent such serious health effects.

Failure to develop an adequate regulation will also result in imposition of a federal program. Meeting the basic requirements of the law and its associated regulations will ensure that Virginia retains its rights to govern Virginia sources.

STATEMENT OF ESTIMATED IMPACT

1. Entities Affected

Approximately 140 sources have a permit to burn pathological waste in Virginia. About 10 percent of these have shut down, plan to shut down, or are otherwise not using their incinerator.

The remainder are primarily small units located at facilities such as hospitals, veterinary offices, and research facilities; there is one large commercial facility.

2. Fiscal Impact

a. Costs to Affected Entities

According to EPA, sources are expected to experience average price increases in the range of 0.00 to 0.16 percent, depending on the industry. These industries are expected to experience output and employment impacts in the range of 0.0 to 0.21 percent. In addition, the revenue impacts for these industries are expected to range from an increase of 0.05 percent to a decrease of 0.05 percent. For hospitals, 0.03 percent is estimated as the price increase necessary to recover annual control costs. The expected average price increase for each hospital patient-day is expected to be less than \$0.35. The average price impact for the commercial incinerator industry is approximately a 4.1 percent increase in price.

Facilities with onsite HMIWI that are currently uncontrolled may experience impacts ranging from 0.03 to 1.70 percent, depending on the industry. For many of these facilities, the economic impacts of switching to an alternative method of waste disposal are much lower than the economic impacts of choosing to install emission control equipment. The decision to switch to an alternative method of waste disposal should preclude facilities from experiencing a significant economic impact. The impacts that

would be incurred by medical/infectious waste generators that currently use an offsite waste incineration service will be negligible.

b. Costs to Localities

The projected cost of the regulation on localities is not expected to be beyond that of other affected entities and are addressed in paragraph 2a above.

c. Costs to Agency

HMIWIs have been regulated by the board since 1972. A system of inspection is well-developed, and regional office staff are familiar with these sources. Therefore, although some new information must be checked for and analyzed, it is not extensive. Therefore, it is not expected that the regulation will result in any cost to the Department of Environmental Quality beyond that currently in the budget. The source of Department funds to carry out this regulation is the federal trust (permit fees charged to affected entities under the permit program). The activities are budgeted under the following program (code)/subprogram (code): Environmental Resources Management (5120000)/Air Quality Stationary Source Regulation Enforcement (5121400). The costs are expected to be ongoing.

Additionally, it is anticipated that as a result of this regulation affected sources will seek alternatives to incineration, thus reducing departmental costs.

d. Benefits

A number of industries will benefit from implementation of the regulation. Companies that provide alternative disposal technologies such as steam autoclaving, microwave irradiation, macrowave irradiation, chemical treatment, thermal treatment, and biological treatment will likely see an increase in customers. These types of treatments are also generally more cost-effective than incineration, and switching to these treatments will save the waste generator money. Additionally, air pollution control device vendors are expected to experience an increase in demand for their products. This regulation is expected to shift demand from smaller incinerators to larger incinerators, thereby benefitting large commercial incinerators.

The regulation will benefit the Commonwealth by helping to prevent air pollution, the source of damage to health, welfare, and property. While no specific data on the cost benefits from the controls are available, costs are, to a degree, offset by the benefits in human health and welfare, including a reduction in the number of cancer cases and other disease, reduction in structural damage, and an increase in welfare factors such as visibility.

Benefits to the Department and Board stemming from the regulation include better determination of compliance and monitoring, as well as a better knowledge of emissions in an affected area. The regulation will also provide specific standards that ensure statewide regulatory consistency.

Finally, implementation of a Virginia program will ensure Virginia management of Virginia sources without federal intervention.

e. Small Business Impact

The impact upon facilities that meet the definition of small business provided in § 9-199 of the Code of Virginia is addressed in paragraph 2a above.

STATEMENT OF PROCESS FOR CONSIDERING ALTERNATIVES

As provided in the public participation procedures of the State Air Pollution Control Board, the Department included, in the Notice of Intended Regulatory Action, a description of the Department's alternatives and a request for comments on other alternatives and the costs and benefits of the Department's alternatives or any other alternatives that the commenters provided.

Following the above, alternatives to the proposed regulation were considered by the Department. The Department determined that the first alternative is appropriate, as it is the least burdensome and least intrusive alternative that fully meets the purpose of the regulation. The alternatives considered by the Department, along with the reasoning by which the Department has rejected any of the alternatives being considered, are discussed below.

1. Amend the regulations to satisfy the provisions of the law and associated regulations and policies. This option is being selected because it meets the stated purpose of the regulatory action: to comply with the requirements of the federal Clean Air Act.
2. Make alternative regulatory changes to those required by the provisions of the law and associated regulations and policies. This option is not being selected because it will not ensure consistency with federal requirements.
3. Take no action to amend the regulations. This option is not being selected because it will result in the imposition of a federal program.

ASSURANCE OF CLARITY

The agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

EVALUATION SCHEDULE AND GOALS

The Department will initiate a review and re-evaluation of the regulation to determine if it should be continued, amended, or terminated within three years after its effective date.

The specific and measurable goals the regulation is intended to achieve are as follows:

1. To protect public health and welfare with the least possible cost and intrusiveness to the citizens and businesses of the Commonwealth.
2. To ensure that owners comply with air pollution emission limits and control technology requirements in order to control levels of designated pollutants being emitted into the ambient air.
3. To ensure the destruction of potentially hazardous materials, and to reduce the physical bulk of material placed within landfills.

SUMMARY AND ANALYSIS OF PUBLIC INPUT

Pursuant to the Board's regulatory public participation procedures (9 VAC 5 Chapter 170, Part IV), the Department of Environmental Quality published a notice of intended regulatory action concerning hospital/medical/infectious waste incinerators (HMIWIs).

A public meeting was advertised accordingly and held by the Department in Richmond on November 25, 1998. The purpose of the proposed action may be found below followed by a summary of the public participation process and an analysis of the public input, along with the basis for the decision of the Board.

PURPOSE OF PROPOSED ACTION

The purpose of the proposed action is to develop a regulation for existing hospital/medical/infectious waste incinerators that meets the requirements of the federal Clean Air Act, and 40 CFR Part 63 Subpart Ce of federal regulations.

SUMMARY OF PUBLIC PARTICIPATION PROCESS

A public meeting was held in Richmond on November 25, 1998. Seven persons attended the meeting, none of whom offered comments; and one written comment was received during the comment period. As provided in the Board's public participation guidelines, notice of the meeting was given to the public on October 26, 1998 in the

Virginia Register. In addition, personal notice of the meeting and the opportunity to comment was given by mail to those persons (about 1,000) on the Department's list to receive notices of intended regulatory actions. A list of meeting attendees and the complete text or an account of each person's input is included in the meeting report which is on file at the Department.

ANALYSIS OF TESTIMONY

Below is a summary of each person's input and the accompanying analysis. Included is the subject of the comment, the identification of the commenter, the text of the comment and the Board's response (analysis and action taken). Each issue is discussed in light of all of the comments received that affect that issue. The Board has reviewed the comments and developed a specific response based on its evaluation of the issue raised. The Board's action is based on consideration of the overall goals and objectives of the air quality program and the intended purpose of the regulation.

1. **SUBJECT:** Typographical errors.

COMMENTER: BFI Waste Systems of North America, Inc.

TEXT: 40 CFR 60.37e(d)(3) and 60.57c(d) contain typographical errors: these sections should properly refer to "for 75 percent of the operating hours per day [and] for 90 percent of the operating days" Otherwise, rather than requiring that the monitoring data be recorded for 75 percent of each day for 9 out of 10 days--which was clearly EPA's intention in drafting the provision--monitoring data would be required to be recorded at least 75 percent of the time. In other words, the inclusion of the word "and" makes the rest of the sentence redundant.

As written, the EPA language would essentially mandate that if the monitoring system fails or malfunctions, facilities must either correct the problem or shut down in six hours or less. This would effectively require the installation and maintenance of an entirely redundant data acquisition system to "back up" the primary system (including field instrumentation). The deletion of the word "and" would result in a requirement that complete data records be maintained for 18 hours a day (for continuous operation) for 90 percent of the operating days per quarter.

We have communicated this issue to EPA's Office of Air Quality Planning and Standards, and request that the Department do so as well.

RESPONSE: EPA has stated that this is indeed a typographical error which will be corrected by technical amendment or in the federal plan. This comment is therefore acceptable, and the proposal has been revised accordingly.

SUMMARY OF PROPOSED REGULATION REVISION S97

CONCERNING
HOSPITAL/MEDICAL/INFECTIOUS WASTE INCINERATORS
(9 VAC 5 CHAPTER 40)

The regulation concerns hospital/medical/infectious waste incinerators (HMIWIs) and is summarized below:

The proposed regulation is intended to meet federal requirements for HMIWIs, which are the source of emissions known or suspected to cause serious health effects. The proposal includes emission limits for particulate matter, carbon monoxide, dioxins/furans, hydrogen chloride, sulfur dioxide, nitrogen oxides, lead, cadmium, and mercury. Special HMIWI operator training and qualification requirements are included in order to assure proper facility operation and compliance with the emissions limitations; sources are also required to prepare overall waste management plans. Compliance, emissions testing, and monitoring requirements are delineated, as well as recordkeeping and reporting of such test results. Finally, specific compliance schedules are provided.

COMMONWEALTH OF VIRGINIA
STATE AIR POLLUTION CONTROL BOARD

SUPPORT DOCUMENT FOR
PROPOSED REGULATION REVISION S97
CONCERNING

HOSPITAL/MEDICAL/INFECTIOUS WASTE INCINERATORS
(9 VAC 5 CHAPTER 40)

STATEMENT OF LEGAL AUTHORITY

Section 10.1-1308 of the Virginia Air Pollution Control Law (Title 10.1, Chapter 13 of the Code of Virginia) authorizes the State Air Pollution Control Board to promulgate regulations abating, controlling and prohibiting air pollution in order to protect public health and welfare. Written assurance from the Office of the Attorney General that the State Air Pollution Control Board possesses the statutory authority to promulgate the proposed regulation is attached.

STATEMENT OF PURPOSE, SUBSTANCE, ISSUES, BASIS AND IMPACT

- A. Purpose - The purpose of the regulation is to establish emission standards that will require the owners of hospital/medical/infectious waste incinerators (HMIWIs) to limit emissions of organics (such as dioxins/furans), metals (such as particulate matter), and acid gases (such as sulfur dioxide and hydrogen chloride) to a specified level necessary to protect public health and welfare. The regulation is being proposed to meet the requirements of § 111(d) and § 129 of the federal Clean Air Act, and 40 CFR Part 60 Subpart Ec of federal regulations.
- B. Substance - The major provisions of the proposal are summarized below:
1. The regulation identifies the sources and geographic areas to which the regulation applies, as well as exemptions [9 VAC 5-40-6000].
 2. Terms unique to the article are defined [9 VAC 5-40-6010].
 3. Emission limits for particulate matter, carbon monoxide, dioxins/furans, hydrogen chloride, sulfur dioxide, nitrogen oxides, lead, cadmium, and mercury are established [9 VAC 5-40-6020 through 9 VAC 5-40-6100].
 4. Cross references to existing state requirements for visible emissions, fugitive dust/emissions, odor, and toxic pollutants are provided [9 VAC 5-40-6110 through 9 VAC 5-40-6140].
 5. HMIWI operator training and qualification requirements are specified [9 VAC 5-40-6150].

6. Waste management plans are required. The regulation includes required elements of such plans, which are intended for sources to separate certain components of solid waste from the health care waste stream in order to reduce the amount of toxic emissions from the incinerated waste [9 VAC 5-40-6160].

7. The regulation requires that sources achieve and maintain compliance with the emission limitations and work practices, along with requirements for inspections; compliance, emissions testing, and monitoring; recordkeeping and reporting; and compliance schedules [9 VAC 5-40-6170 through 9 VAC 5-40-6200].

8. Cross references to existing state requirements for registration, facility and control equipment maintenance or malfunction; and permits are provided [9 VAC 5-40-6210 through 9 VAC 5-40-6230].

C. Issues - The primary advantages and disadvantages of implementation and compliance with the regulation by the public and the Department are discussed below.

1. Public: A limited segment of the general public may experience an economic disadvantage in increased fees where affected HMIWIs must install pollution control systems. However, the general public will experience a number of health and welfare advantages. HMIWI emissions cause a number of serious health effects, including cancer. Therefore, reduction of these emissions will reduce disease and its related costs. Reduction of HMIWI emissions will also reduce the risk of damage to vegetation and property, which will in turn enhance property values, tax revenues, payroll, and other socioeconomic components. Generally, the wide availability of alternatives to incineration will limit disadvantages, and may in fact provide a benefit in the form of reduced costs.

A limited number of HMIWIs may experience an economic disadvantage if they must install pollution control systems. HMIWIs as well as industry in general will also benefit from the rule: overall ozone reductions may lessen the risk of current attainment areas being designated nonattainment, and current nonattainment areas being reclassified to a more serious classification.

2. Department: The Department may need to perform additional inspection, monitoring and recordkeeping to ensure that the emissions limitations are being met, which will require increased expenditure in personnel and equipment. However, the increase in data to be gathered and analyzed will benefit the Department by enhancing its ability to make both short- and long-term planning decisions. Furthermore, these sources have been, for the most part, permitted, inspected, and monitored for many years, therefore, little new additional new effort will be expended. It is anticipated that more sources will seek alternatives to incineration, thereby reducing the number of sources the department will need to inspect and monitor.

D. Basis - The legal basis for the proposed regulation is the Virginia Air Pollution Control Law (Title 10.1, Chapter 13 of the Code of Virginia), specifically § 10.1-1308 which authorizes the Board to promulgate regulations abating, controlling and prohibiting air pollution in order to protect public health and welfare.

- E. Economic Impact Analysis - The Department of Planning and Budget prepared an economic impact analysis for the proposal as required by § 9-6.14:7.1 G of the Administrative Process Act. The Department of Environmental Quality takes no issue with the economic impact analysis prepared by the Department of Planning and Budget.